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MEZLIN®

Sterile mezlocillin sodium
for intravenous or intramuscular use

BRIEF SUMMARY

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MICROBIOLOGY

Mezlocillin is a bactericidal antibiotic which acts by interfering with synthesis of cell-wall components. It is active against a variety of gram-negative and gram-positive bacteria, including aerobic and anaerobic strains. Mezlocillin is usually active *in vitro* against most strains of the following organisms:

Gram-negative bacteria

Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii (formerly P. morganii), Providencia rettgeri (formerly Proteus rettgeri), Providencia stuartii, Citrobacter species Klebsiella species (including K. pneumoniae), Enterobacter species, Shigella species* Pseudomonas aeruginosa* (and other species), *Haemophilus influenzae, Haemophilus parainfluenzae, Neisseria* species. Many strains of *Serratia, Salmonella** and *Acinetobacter** are also susceptible.

Gram-positive bacteria

Staphylococcus aureus (non-penicillinase producing strains), Beta-hemolytic streptococci (Groups A and B), *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Streptococcus faecalis* (enterococcus).

Anaerobic Organisms

Peptococcus species, Peptostreptococcus species, Clostridium species Fusobacterium species* Veillonella species* Eubacterium* species, Bacteroides species including *B. fragilis* group).

*Mezlocillin has been shown to be active *in vitro* against these organisms, however clinical efficacy has not yet been established.

Noteworthy is mezlocillin's broadened spectrum of *in vitro* activity against important pathogenic aerobic gram-negative bacteria, including strains of *Pseudomonas, Klebsiella, Enterobacter, Serratia, Proteus, Escherichia* and *Haemophilus*, as well as *Bacteroides* and other anaerobes, and its excellent inhibitory effect against gram-positive organisms including *Streptococcus faecalis* (enterococcus). It is inactive against penicillinase-producing strains of *Staphylococcus aureus*.

In vitro studies have shown that mezlocillin combined with an aminoglycoside (e.g., gentamicin, tobramycin, amikacin, sisomicin) acts synergistically against strains of *Streptococcus faecalis* and *Pseudomonas aeruginosa*. In some instances, this combination also acts synergistically *in vitro* against other gram-negative bacteria such as *Serratia, Klebsiella* and *Acinetobacter* species.

Mezlocillin is slightly more active when tested at alkaline pH and, as with other penicillins, has reduced activity when tested *in vitro* with increasing inoculum. The minimum bactericidal concentration (MBC) generally exceeds the minimum inhibitory concentration (MIC) by a factor of 2 or 3. Resistance to mezlocillin *in vitro* develops slowly (multiple step mutation). Some strains of *Pseudomonas aeruginosa* have developed resistance fairly rapidly. Mezlocillin is not stable in the presence of penicillinase and strains of *Staphylococcus aureus* resistant to penicillin are also resistant to mezlocillin.

Susceptibility Tests

Quantitative methods that require measurement of zone diameters give good estimates of bacterial susceptibility. One such procedure* has been recommended for use with discs to test susceptibility to antimicrobials. When the causative organism is tested by the Kirby-Bauer method of disc susceptibility, a 75 mcg mezlocillin disc should give a zone of 18 mm or greater to indicate susceptibility. Zone sizes of 14 mm or less indicate resistance. Zone sizes of 15 to 17 mm indicate intermediate susceptibility. Susceptible strains of *Haemophilus* and *Neisseria* species give zones of ≥29 mm; resistant strains ≤ 28 mm. With this procedure, a report from the laboratory of "Susceptible" indicates that the infecting organism is likely to respond to therapy. A report of "Resistant" indicates that the infecting organism is not likely to respond to therapy; other therapy should be selected. A report of "Intermediate Susceptibility" suggests that the organism may be susceptible if the infection is confined to tissues and fluids (e.g., urine), in which high antibiotic levels are attained. The mezlocillin disc should be used for testing susceptibility to mezlocillin. In certain conditions, it may be desirable to do additional susceptibility testing by broth or agar dilution techniques. Dilution methods, preferably the agar plate dilution procedure, are most accurate for susceptibility testing of obligate anaerobes. *Enterobacteriaceae, Pseudomonas* species and *Acinetobacter* species are considered susceptible if the MIC of mezlocillin is no greater than 64 mcg/ml and are considered resistant if the MIC is greater than 128 mcg/ml. *Haemophilus* species and *Neisseria* species are considered susceptible if the MIC of mezlocillin is less than or equal to 1 mcg/ml. Mezlocillin standard is available for broth or agar dilution studies.

*Bauer, A.W., Kirby, W.M., Sherris, J.C., and Turck, M.: Antibiotic Testing by a Standardized Single Disc Method. Am. J. Clin. Pathol. 45:493, 1966. Standardized Disc Susceptibility Test. FEDERAL REGISTER, 39: 19182-19184, 1974.

INDICATIONS AND USAGE

MEZLIN is indicated for the treatment of serious infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

Lower Respiratory Tract Infections including pneumonia and lung abscess caused by *Haemophilus influenzae; Klebsiella* species including *K. pneumoniae, Proteus mirabilis, Pseudomonas* species including *P. aeruginosa, E. coli*, and *Bacteroides* species including *B. fragilis*.

Intra-Abdominal Infections including acute cholecystitis, cholangitis, peritonitis, hepatic abscess and intra-abdominal abscess caused by susceptible *E. coli, Proteus mirabilis, Klebsiella* species, *Pseudomonas* species, *S. faecalis* (enterococcus), *Bacteroides* species, *Peptococcus* species, and *Peptostreptococcus* species.

Urinary Tract Infections caused by susceptible *E. coli, Proteus mirabilis*, the indole positive *Proteus* species, *Morganella morganii, Klebsiella* species, *Enterobacter* species, *Serratia* species, *Pseudomonas* species, *S. faecalis* (enterococcus).

Uncomplicated gonorrhea due to susceptible *Neisseria gonorrhoeae*.

Gynecological Infections including endometritis, pelvic cellulitis, and pelvic inflammatory disease associated with susceptible *Neisseria gonorrhoeae, Peptococcus* species, *Peptostreptococcus* species, *Bacteroides* species, *E. coli, Proteus mirabilis, Klebsiella* species, and *Enterobacter* species.

Skin and Skin Structure Infections caused by susceptible *S. faecalis* (enterococcus), *E. coli, Proteus mirabilis*, the indole positive *Proteus* species, *Proteus vulgaris* and *Providencia rettgeri, Klebsiella* species, *Enterobacter* species, *Pseudomonas* species, *Peptococcus* species, and *Bacteroides* species.

Septicemia including bacteremia caused by susceptible *E. coli, Klebsiella* species, *Enterobacter* species, *Pseudomonas* species, *Bacteroides* species, and *Peptococcus* species.

Mezlocillin has also been shown to be effective for the treatment of infections caused by *Streptococcus* species including Group A Beta-hemolytic *Streptococcus* and *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*); however, infections caused by these organisms are ordinarily treated with more narrow spectrum penicillins.

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing infection and to determine their susceptibility to mezlocillin. Therapy with MEZLIN may be initiated before results of these tests are known; once results become available, appropriate therapy should be continued.

Mezlocillin's broad spectrum of activity makes it particularly useful for treating mixed infections caused by susceptible strains of both gram-negative and gram-positive aerobic or anaerobic bacteria. It is not effective, however, against infections caused by penicillinase-producing *Staphylococcus aureus*.

In certain severe infections, when the causative organisms are unknown, MEZLIN may be administered in conjunction with an aminoglycoside or a cephalosporin antibiotic as initial therapy. As soon as results of culture and susceptibility tests become available, antimicrobial therapy should be adjusted if indicated. Culture and sensitivity testing, performed periodically during therapy, will provide information on the therapeutic effect of the antimicrobial and will monitor for the possible emergence of bacterial resistance.

MEZLIN has been used effectively in combination with an aminoglycoside antibiotic for the treatment of life-threatening infections caused by *Pseudomonas aeruginosa*. For the treatment of febrile episodes in immunosuppressed patients with granulocytopenia, MEZLIN should be combined with an aminoglycoside or a cephalosporin antibiotic.

CONTRAINDICATIONS

MEZLIN is contraindicated in patients with a history of hypersensitivity reactions to any of the penicillins.

WARNINGS

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have occurred in patients receiving a penicillin. These reactions are more apt to occur in individuals with a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Before therapy with mezlocillin is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to penicillins, cephalosporins or other drugs. Antibiotics should be used with caution in any patient who has demonstrated some form of allergy, particularly to drugs.

If an allergic reaction occurs during therapy with mezlocillin, the drug should be discontinued. SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE PROVIDED AS INDICATED.

PRECAUTIONS

Although MEZLIN shares with other penicillins the low potential for toxicity as with any potent drug, periodic assessment of organ system functions, including renal, hepatic and hematopoietic is advisable during prolonged therapy.

Bleeding manifestations have occurred in some patients receiving beta-lactam antibiotics. These reactions have been associated with abnormalities of coagulation tests, such as clotting time, platelet aggregation and prothrombin time and are more likely to occur in patients with renal impairment. Although MEZLIN has rarely been associated with any bleeding abnormalities, the possibility of this occurring should be kept in mind, particularly in patients with severe renal impairment receiving maximum doses of the drug.

MEZLIN has only rarely been reported to cause hypokalemia, however the possibility of this occurring should also be kept in mind, particularly when treating patients with fluid and electrolyte imbalance. Periodic monitoring of serum potassium may be advisable in patients receiving prolonged therapy.

MEZLIN is a monosodium salt containing only 42.6 mg (1.85 mEq) of sodium per gram of mezlocillin. This should be considered when treating patients requiring restricted salt intake.

As with any penicillin, an allergic reaction, including anaphylaxis, may occur during MEZLIN administration, particularly in a hypersensitive individual.

As with other antibiotics, prolonged use of MEZLIN may result in overgrowth of non-susceptible organisms. If this occurs, appropriate measures should be taken.

Antimicrobials used in high doses for short periods to treat gonorrhea may mask or delay the symptoms of incubating syphilis. Therefore, prior to treatment, patients with gonorrhea should also be evaluated for syphilis. Specimens for dark field examination should be obtained from any suspected primary lesion and serologic tests should be performed. Patients treated with MEZLIN should undergo follow-up serologic tests for three months after therapy.

Interactions with Drugs and Laboratory Tests

As with other penicillins, the mixing of mezlocillin with an aminoglycoside in solutions for parenteral administration can result in substantial inactivation of the aminoglycoside.

Probenecid interferes with the renal tubular secretion of mezlocillin, thereby increasing serum concentrations and prolonging serum half-life of the antibiotic.

High urine concentrations of mezlocillin may produce false positive protein reactions (pseudoproteinuria) with the following methods: sulfosalicylic acid and boiling test, acetic acid test, biuret reaction, and nitric acid test. The bromphenol blue (Multi-stix®) reagent strip test has been reported to be reliable.

Pregnancy Category B

Reproduction studies have been performed in rats and mice at doses up to 2 times the human dose, and have revealed no evidence of impaired fertility or harm to the fetus due to MEZLIN. There are however no adequate and well controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Mezlocillin crosses the placenta and is found in low concentrations in cord blood and amniotic fluid.

Nursing Mothers

Mezlocillin is detected in low concentrations in the milk of nursing mothers; therefore caution should be exercised when MEZLIN is administered to a nursing woman.

ADVERSE REACTIONS

As with other penicillins, the following adverse reactions may occur:

Hypersensitivity reactions: skin rash, pruritus, urticaria, drug fever, and anaphylactic reactions.

Gastro-intestinal disturbances: abnormal taste sensation, nausea, vomiting and diarrhea.

Hemic and Lymphatic Systems: thrombocytopenia, leukopenia, neutropenia, eosinophilia and reduction of hemoglobin or hematocrit.

Abnormalities of hepatic and renal function tests: elevation of serum aspartate aminotransferase (SGOT), serum alanine aminotransferase (SGPT), serum alkaline phosphatase, serum bilirubin. Elevation of serum creatinine and/or BUN. Reduction in serum potassium.

Central nervous system: convulsive seizures or neuromuscular hyperirritability.

Local reactions: thrombophlebitis with intravenous administration, pain with intramuscular injection.

OVERDOSAGE

As with other penicillins, MEZLIN in overdosage has the potential to cause neuromuscular hyperirritability or convulsive seizures. Hemodialysis, if necessary, will aid in removal of the drug from the blood.

DOSAGE AND ADMINISTRATION

MEZLIN (sterile mezlocillin sodium) may be administered intravenously or intramuscularly. For serious infections, the intravenous route of administration should be used. Intramuscular doses should not exceed 2g per injection.

The recommended adult dosage for serious infections is 200-300 mg/kg per day given in 4 to 6 divided doses. The usual dose is 3g given every 4 hours (18g/day) or 4g given every 6 hours (16g/day). For life-threatening infections, up to 350 mg/kg per day may be administered, but the total daily dosage should ordinarily not exceed 24g.

MEZLIN DOSAGE GUIDE (ADULTS)

Condition	Daily Dosage Range	Usual Daily Dosage	Frequency and Route of Administration
Urinary tract infection (uncomplicated)	100-125 mg/kg	6-8g	1.5-2g every 6 hours IV or IM
Urinary tract infection (complicated)	150-200 mg/kg	12g	3g every 6 hours IV
Lower respiratory tract infection Intra-abdominal infection Gynecological infection Skin & skin structure infection Septicemia	225-300 mg/kg	16-18g	4g every 6 hours or 3g every 4 hours IV

For patients with life-threatening infections, 4g may be administered every 4 hours (24g/day).

Dosage for any individual patient must take into consideration the site and severity of infection, the susceptibility of the organisms causing infection, and the status of the patient's host defense mechanism.

The duration of therapy depends upon the severity of infection. Generally, MEZLIN should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration is 7 to 10 days, however, in difficult and complicated infections, more prolonged therapy may be required. Antibiotic therapy for Group A beta-hemolytic streptococcal infections should be maintained for at least 10 days to reduce the risk of rheumatic fever or glomerulonephritis.

In certain deep-seated infections, involving abscess formation, appropriate surgical drainage should be performed in conjunction with antimicrobial therapy.

For acute, uncomplicated gonococcal urethritis, the usual dose is 1-2g given once intravenously or by intramuscular injection. Probenecid 1g may be given orally at the time of dosing or up to 1/2-hour before. (For full prescribing information, refer to probenecid package insert).

MEZLIN DOSAGE GUIDE FOR PATIENTS WITH IMPAIRED RENAL FUNCTION

Creatinine Clearance ml/min	Urinary Tract Infection (Uncomplicated)	Urinary Tract Infection (Complicated)	Serious Systemic Infection
>30	Usual Recommended Dosage		
10-30	1.5g every 8 hours	1.5g every 6 hours	3g every 8 hours
<10	1.5g every 8 hours	1.5g every 8 hours	2g every 8 hours

For life-threatening infections, 3g may be given every 6 hours to patients with creatinine clearances between 10-30 ml/min and 2g every 6 hours to those with clearances less than 10 ml/min.

For patients with serious systemic infection undergoing hemodialysis for renal failure, 3-4g may be administered after each dialysis and then every 12 hours. Patients undergoing peritoneal dialysis may receive 3g every 12 hours.

For patients with renal failure and hepatic insufficiency, measurement of serum levels of mezlocillin will provide additional guidance for adjusting dosage.

MEZLIN DOSAGE GUIDE (NEWBORNS)

BODY WEIGHT (gm)	AGE	
	≤7 DAYS	>7 DAYS
≤2000	75 mg/kg every 12 hours (150 mg/kg/day)	75 mg/kg every 8 hours (225 mg/kg/day)
>2000	75 mg/kg every 12 hours (150 mg/kg/day)	75 mg/kg every 6 hours (300 mg/kg/day)

For infants beyond one month of age and children up to the age of 12 years, 50 mg/kg may be administered every 4 hours (300 mg/kg/day).

The drug may be infused intravenously over 30 minutes or be given by intramuscular injection.

Miles Pharmaceuticals
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West Haven, Connecticut 06516 USA
Issued: July 1981 Printed in U.S.A. PD100553 18078

Miles Pharmaceuticals
Division of Miles Laboratories, Inc.
400 Morgan Lane
West Haven, Connecticut 06516 MLO-220

Effective single-dose prophylaxis* (1.5 g IV ½ to 1 hour before surgery)

ZINACEF® IM/IV GLAXO

sterile cefuroxime sodium

1.5 g vials

- A record of success in preventing septic complications following cholecystectomy[1-3]
- Serum levels exceed the *in vitro*† geometric mean MIC for *Staphylococcus aureus* for over 8 hours and for *Escherichia coli* for approximately 7 hours following a 1.5 g IV dose[4,5]
- Reaches "...therapeutic levels in the gallbladder wall, the main site of the inflammatory reaction."[3]
- Classic cephalosporin safety profile

*In clean-contaminated or potentially contaminated surgical procedures.

†Although useful guides, *in vitro* activity and pharmacokinetic data do not necessarily correlate with clinical response.

References: 1. Murray WR, Bradley JA: Antibiotic prophylaxis in elective biliary surgery. *Res Clin Forums* 1983;5:97-102. **2.** McArdle CS, Morran CG, Thomson G, et al: Prophylactic cefuroxime in biliary surgery. *Res Clin Forums* 1983;5:65-71. **3.** Thomas M, Browning AK, McFarland RJ: Excretion of cefuroxime in biliary disease. *Surg Gynecol Obstet* 1984;158:272-274. **4.** Browning AK, House CA: Pharmacokinetics of cefuroxime compared to other cephalosporins. *Cefuroxime Update*, Royal Society of Medicine International Congress and Symposium Series No. 38, 1981, pp 87-99. **5.** Grimm H, Rangoowala R: Bakteriologische in-vitro untersuchungen mit cefotaxim im vergleich zu cefuroxim und cefazolin. *Infection* 1980:8(suppl 4)S385-S387.

Brief summary. Before prescribing, consult complete prescribing information.

CONTRAINDICATIONS

ZINACEF® (sterile cefuroxime sodium, Glaxo) is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

BEFORE THERAPY WITH ZINACEF® IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. IF AN ALLERGIC REACTION TO ZINACEF OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad-spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad-spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*.

Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte, and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should also be considered.

PRECAUTIONS

Although ZINACEF® (sterile cefuroxime sodium, Glaxo) rarely produces alterations in kidney function, evaluation of renal status during therapy is recommended, especially in seriously ill patients receiving the maximum doses. Cephalosporins should be given with caution to patients receiving concurrent treatment with potent diuretics as these regimens are suspected of adversely affecting renal function.

The total daily dose of ZINACEF should be reduced in patients with transient or persistent renal insufficiency (see **DOSAGE AND ADMINISTRATION**), because high and prolonged serum antibiotic concentrations can occur in such individuals from usual doses.

As with other antibiotics, prolonged use of ZINACEF may result in overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection does occur during therapy, appropriate measures should be taken.

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Nephrotoxicity has been reported following concomitant administration of aminoglycoside antibiotics and cephalosporins.

Interference with Laboratory Tests A false positive reaction for glucose in the urine may occur with copper reduction tests (Benedict's or Fehling's solution or with Clinitest® tablets), but not with enzyme-based tests for glycosuria (eg, Tes-Tape®). As a false negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase method be used to determine blood plasma glucose levels in patients receiving ZINACEF. Cefuroxime does not interfere with the assay of serum and urine creatinine by the alkaline picrate method.

Carcinogenesis, Mutagenesis, and Impairment of Fertility Although no long-term studies in animals have been performed to evaluate carcinogenic potential, no mutagenic potential of cefuroxime was found in standard laboratory tests.

Reproductive studies revealed no impairment of fertility in animals.

Usage in Pregnancy *Pregnancy Category B*: Reproduction studies have been performed in mice and rabbits at doses up to 60 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefuroxime. There are, however, no adequate well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers Since ZINACEF is excreted in human milk, caution should be exercised when ZINACEF is administered to a nursing woman.

Pediatric Use Safety and effectiveness in children below the age of 3 months have not been established. Accumulation of other members of the cephalosporin class in newborn infants (with resulting prolongation of drug half-life) has been reported.

ADVERSE REACTIONS

ZINACEF® (sterile cefuroxime sodium, Glaxo) is generally well tolerated. The most common adverse effects have been local reactions following intravenous administration. Other adverse reactions have been encountered only rarely.

Local Reactions Thrombophlebitis has occurred with intravenous administration in 1 in 60 patients.

Gastrointestinal Gastrointestinal symptoms occurred in 1 in 150 patients and included diarrhea (1 in 220 patients) and nausea (1 in 440 patients). Symptoms of pseudomembranous colitis can appear during or after antibiotic treatment.

Hypersensitivity Reactions Hypersensitivity reactions have been reported in less than 1% of the patients treated with ZINACEF and include rash (1 in 125). Pruritus and urticaria and positive Coombs' test each occurred in less than 1 in 250 patients.

Blood A decrease in hemoglobin and hematocrit has been observed in 1 in 10 patients and transient eosinophilia in 1 in 14 patients. Less common reactions seen were transient neutropenia (less than 1 in 100 patients) and leukopenia (1 in 750 patients). A similar pattern and incidence was seen with other cephalosporins used in controlled studies.

Hepatic Transient rise in SGOT and SGPT (1 in 25 patients), alkaline phosphatase (1 in 50 patients), LDH (1 in 75 patients) and bilirubin (1 in 500 patients) levels has been noted.

Kidney Elevations in serum creatinine and/or blood urea nitrogen and a decreased creatinine clearance have been observed, but their relationship to cefuroxime is unknown.

DOSAGE AND ADMINISTRATION

Adults The usual adult dosage range for ZINACEF® (sterile cefuroxime sodium, Glaxo) is 750 mg to 1.5 g every 8 hours, usually for 5-10 days. In uncomplicated urinary tract infections, skin and skin structure infections, disseminated gonococcal infections, and uncomplicated pneumonia, a 750 mg dose every 8 hours is recommended. In severe or complicated infections, a 1.5 g dose every 8 hours is recommended. In life-threatening infections or infections due to less susceptible organisms, 1.5 g every 6 hours may be required. In bacterial meningitis, the dose should not exceed 3.0 g every 8 hours. The recommended dose for uncomplicated gonococcal infection is 1.5 g intramuscularly given as a single dose at two different sites together with 1.0 g of oral probenecid. For preventive use for clean-contaminated or potentially contaminated surgical procedures, a 1.5 g dose administered intravenously just prior to surgery (approximately ½ to 1 hour before the initial incision) is recommended. Thereafter, give 750 mg intravenously or intramuscularly every 8 hours when the procedure is prolonged.

For preventive use during open heart surgery, a 1.5 g dose administered intravenously at the induction of anesthesia and every 12 hours thereafter for a total of 6.0 g is recommended.

Impaired Renal Function When renal function is impaired, a reduced dosage must be employed. Dosage should be determined by the degree of renal impairment and the susceptibility of the causative organism. See full prescribing information for dosage in patients with impaired renal function.

HOW SUPPLIED

ZINACEF® (sterile cefuroxime sodium, Glaxo) is a dry, white to off-white powder supplied in vials and infusion bottles. Each vial contains cefuroxime sodium equivalent to 750 mg or 1.5 g cefuroxime. ZINACEF in the dry state should be stored at controlled room temperature and protected from light.

NDC 0173-0352-30	750 mg Vials (10 singles)
NDC 0173-0352-31	750 mg Vials (Tray of 25)
NDC 0173-0354-34	1.5 g Vials (10 singles)
NDC 0173-0354-35	1.5 g Vials (Tray of 25)
NDC 0173-0353-32	750 mg Infusion Pack (Tray of 10)
NDC 0173-0356-32	1.5 g Infusion Pack (Tray of 10)

Glaxo Glaxo Inc., Research Triangle Park, NC 27709

ZIN263